

2498/101

APPENDIX C

Summary of Telephone Interview of March 2, 2004 with Examiner Peter Paras, Supervisory Examiner Amy Nelson, and Technology Specialist Anthony Caputa regarding U.S. Application No. 09/472,558 to Bahramian et al.

Bruce Sunstein and Barbara J. Carter were present representing the Applicants, in addition to the above-mentioned personnel from the USPTO. As a first point, it was made of record that currently pending claim 11 is free of rejections and objections under 35 USC § 112.

Second, it was clarified that prior art reference PCT/US93/10756 was cited only with respect to the issue of collagen being a known target for suppression, muting, silencing, etc. in combination with the Fire et al. patent (US6,506,559) as part of a 35 USC §103(a) rejection of claims 57-59 and 69, so no further discussion of this reference occurred.

Third, discussion focused on the Fire reference relative to draft claim 11, submitted for discussion during this interview. Mr. Sunstein and Ms. Carter asserted that the presently claimed invention is distinguishable from Fire because Fire requires the DNA, if added to a cell, to be expressed, i.e. transcribed, into double-stranded RNA, and discloses that it is the RNA that silences the genes. There was a question as to whether Fire was enabling regarding disclosure of ds-DNA for muting/silencing a target gene. Further, Fire does not disclose a screening method to identify muting sequences of double-stranded DNA that mute at the level of post-transcription.

A consensus seemed to be reached that claim 11, may be free of the prior art, if agreement can be reached on functional language [in step (a)(ii)] regarding what it is about the muting DNA found by screening that is structurally/compositionally distinct from both Fire and the possibility of prior art directed towards transcription blockers. Ms. Carter pointed out that Gamborotta et al, previously cited in the Office Action of August 13, 2002, was just such a transcription-blocker reference, and the Gamborotta reference had been successfully overcome with Response F, as indicated in the Office Action of May 6, 2003. Ms. Carter questioned whether applicants would be required to re-address such art at this point in the prosecution. Also, a question regarding the meaning of the term homologous was raised by Examiner Nelson.

Mr. Sunstein re-capped where he thought things stood with respect to claim 11, and during this re-cap, it became clear that Examiner Nelson did not realize that the Markush limitation for the group of genes in draft claim 11 was not intended to be part of the draft claim, and that applicants believed claim 11, as written in Response G, with no limitation to gene, and no limitation to animal, was the claim in dispute. At this point, Examiner Nelson said such a claim could only be allowable if free of both Fire and 112 rejections, which prompted the re-statement by Mr. Sunstein, for the record, that it was our understanding that currently pending claim 11, with no gene or animal limitations, was

2498/101

free of 112 rejections. Examiner Nelson indicated that this may not be true, whereupon it was noted by Mr. Sunstein that our frustration with this prosecution, understandably, stemmed from inconsistent rejections – had we or had we not overcome transcription-blocker type references when we successfully overcame the Gamborotta reference in May of 2003; were we or were we not free of 112 rejections with respect to currently pending claim 11?

In summary, a desire for consensus was expressed on the parts of Mr. Sunstein and Ms. Carter. To that end, Mr. Sunstein stated intent to delete all other independent claims except claim 11 in this application. Examiner Nelson suggested that we contact the inventors and come up with a strategy for inserting structural/compositional language into step (a)(ii), in particular, of claim 11, submit it with our response, and hopefully it would satisfy the outstanding issues regarding patentability for the claims of this application. No agreement was reached.